

Grant: HE-05977

Luther Terry, M.D.
Surgeon General
U.S. Public Health Service
Dept. of Health, Education, and Welfare
Bethesda 14, Maryland

Dear Dr. Terry:

The enclosed information, which follows the "Outline for Invention Reports", was requested by Miss Katharine A. Parent in a letter of September 30, 1963.

1. Title of discovery. A totally implanted, controllable cardiac pacemaker.
2. Information about inventor. The writer, Adrian Kantrowitz, M.D., and the General Electric Co. invented the pacemaker. My residence is at 546 East 17th Street, Brooklyn 26, N.Y. My business address is the Department of Surgery, Maimonides Hospital, 4802 Tenth Avenue, Brooklyn 19, N.Y. My official title is Director of Cardio-vascular Surgery. My contribution was the concept of the pacemaker and specifications for its construction. Design of the circuit and components as well as the case and leads of early models was carried out by the General Electric Company's Electronics Laboratory in Syracuse, N.Y. The Company's X-ray Division in Milwaukee, Wis., modified the case and leads for the later models and now has full responsibility for the pacemaker.
3. Facility at which discovery was made. The idea was conceived and preliminary studies were made in the Surgical Research Laboratory at the Edward Neimeth Institute for Medical Research, Maimonides Hospital, Brooklyn.
4. Contribution of facility to discovery. I am a full-time employee of Maimonides Hospital and spend about 50% of my time on research supported by the National Institutes of Health. The Edward Neimeth Institute's contribution included use of laboratory animal quarters and operating rooms, offices, machine shop and electronics laboratory.

5. Patent policies of facility. Article 7 of the By-Laws of Maimonides Hospital states the following patent policies:

"All inventions, discoveries, and improvements made by any person in the employ of the Corporation or while receiving any compensation for his services, or while using any of the facilities of the Hospital, shall be the property of the Corporation to be used by it for the purpose of furthering the medical sciences.

§The Board of Trustees may, however, permit the discoverer or the inventor to participate in the income, if any, from the discovery or invention.

"The provisions of this Article may be waived by the Board of Trustees."

6. Other organizations contributing to discovery. The General Electric Company (Electronics Laboratory, Syracuse, and X-ray Division, Milwaukee) is the only organization involved in this discovery.

7. Contribution of this organization. The pacemaker was designed and constructed entirely at GE's expense in men, money, facilities and materials.

8. Patent policies of this organization. This information may be obtained directly from the General Electric Company.

9. Description of invention. An electronic pacemaker--consisting of 5 batteries, 3 resistors, 2 transistors, and 1 capacitor sealed in a Silastic case--is designed for implantation in an abdominal pocket. The unit weighs 4 oz. and measures 4 x 6 x 1½ cm. The components are arranged to give a 3-volt impulse to the heart every 2 milliseconds via two stainless-steel electrodes passed from the unit and embedded in the myocardium. Also available is an optional external control in a lightweight case connected to an induction coil which is taped on the abdomen over the implanted pacemaker. When the patient is under unusual physical stress, the pulse^{T_{alt}} may be raised anywhere between the internal unit's fixed rate of 65 per minute and 120 per minute.

10. Objectives, advantages, and uses of discovery. The objective is to provide a system for regular and reliable stimulation of the heart in cases where its own intrinsic rhythm has become so seriously disturbed that the patient's life is jeopardized and medical therapy is unavailing. Among the advantages of this pacemaker are its total implantability obviating wires passed through the skin with risk of infection, its small size, light weight, and low power drain. Also,

the pulse rate can be readily increased with the optional external control when desirable, e.g., during periods of stress such as infection or blood loss when the heart rate would normally be accelerated.

11. Importance and usefulness of discovery in U.S. and foreign countries. Implantable cardiac pacemakers are becoming increasingly useful in the treatment of complete heart block with or without Stokes-Adams seizures which at present affects numerous persons in the U.S. and elsewhere. Widespread use of these devices may appreciably reduce the high mortality rate in this patient group.

12. Personal desires on applying for a patent. None.

13. I do not feel qualified to judge whether publication would be adequate to ensure the availability of this discovery to the public.

14. Information on conception of invention and its reduction to actual practice. It became clear to me early in 1960 that a device such as this would return to useful activity many persons suffering from complete heart block. Meetings were arranged with engineers of GE's Electronics Laboratory in Syracuse who reduced the idea to a functioning device during that year.

15. Supporting evidence of item 14. Our laboratory records include voluminous notes on animal experiments as well as observations in human patients during the development and subsequent modifications of the pacemaker.

16. Disclosure of discovery to others. Our experience with the device has been widely disseminated in the scientific community by means of the following published papers and numerous talks at major medical meetings:

Kantrowitz, A., Cohen, R., Raillard, H., and Schmidt, J.: Experimental and clinical experience with a new implantable cardiac pacemaker. Circulation, 24:967, 1961.

Kantrowitz, A.: Electronic physiologic aids. Proc. 3rd IBM Medical Symposium, October 1961, New York.

Kantrowitz, A.: Life support by control of internal environment--artificial hearts, lungs and pacemakers. NEREM Record, November 1961.

Kantrowitz, A.: The physiologic implication of implanted cardiac pacemakers in humans, Excerpta Med., Internat. Congress Series 48, International Congress of Physiological Sciences, No. 761, September 1962.

Kantrowitz, A., Cohen, R., Raillard, H., Schmidt, J. and Feldman, D.S.: The Treatment of complete heart block with an implanted controllable pacemaker. Surg. Gynec. Obstet., 115:415, 1962.

Kantrowitz, A.: Clinical experience with an implanted controllable cardiac pacemaker. Digest 15th Ann. Conf. Engineering in Med. and Biol., p. 64, November 1962.

Kantrowitz, A.: Experimental and clinical experience with a new implantable cardiac pacemaker. Bull. Soc. Int. Chir., 6:691, 1962.

Feldman, D.S. and Kantrowitz, A.: Electrical characteristics of human ventricular myocardium stimulated in vivo. Clin. Res. 11:1:22, January 1963.

Kantrowitz, A.: Complete heart block treated with an implanted controllable cardiac pacemaker. In press (Ann. N.Y. Acad. Sci.).

Dressler, W., Jonas, S., and Kantrowitz, A.: Observation in patients with implanted cardiac pacemaker. I. Clinical experience. Amer. Heart J., 66:325, 1963.

Kantrowitz, A.: Implanted cardiac pacemakers. In press (Ann. N.Y. Acad. Sci.).

Kantrowitz, A.: The Treatment of Stokes-Adams syndrome in heart block. In press (Prog. Cardio. Dis.).

Kantrowitz, A.: Problems in the clinical use of implantable cardiac pacemakers. In press (J. Cardio. Surg.).

Luther Terry, M.D.

-5-

17. General Electric Company engineers involved in development of the pacemaker during 1960 were: J.J. Suran, J.D. Schmidt, and Heinz Raillard. To my knowledge, these engineers are still associated with GE. In our hospital, Richard Cohen, M.D., was involved with me in early experiments and, during development of the pacemaker, D.S. Feldman, M.D., of the Neurology Service made precise studies to determine myocardial needs in relation to electric stimulation.

18. The following reports on use of similar devices were in the literature at the time of the discovery:

Zoll, P.M. - Resuscitation of the heart in ventricular standstill by external electric stimulation. New Engl. J. Med., 247, 1952, 768-771.

Suran, J.J. - Circuit properties of the PNP transistor. Proc. Nat. Conf. Aeronaut. Electronics, May 1956.

Weirich, W.L., Gott, V.L. and Lillehei, C.W. - The treatment of complete heart block by the combined use of a myocardial electrode and an artificial pacemaker. Surg. Forum, 8, 1957, 360-363.

Furman, S. and Robinson, G. - The use of an intracardiac pacemaker in the correction of total heart block. Surg. Forum, 9, 1958, 245-248.

Hunter, S.W., Roth, N.A., Bernardez, D. and Noble, J.L. - A bipolar myocardial electrode for complete heart block. Lancet, 79, 1959, 506-508.

Glenn, W.W.L., Mauro, A., Longo, E., Laviates, P.H. and Mackay, F.J. - Remote stimulation of the heart by radio-frequency transmission. New Engl. J. Med., 261, 1959, 948-951.

Chardack, W.M., Gage, A.A. and Greatbatch, W. - A transistorized, self-contained, implantable pacemaker for the long-term correction of complete heart block. Surgery, 48, 1960, 643-654.

Please do not hesitate to request any further material needed.

Sincerely,

Adrian Kantrowitz, M.D.
Acting Director of Surgery

AK:etg